UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS – EASTERN DIVISION

MARY CRUMPTON, individually and on behalf of all others similarly situated, Plaintiff, v. OCTAPHARMA PLASMA, INC., Defendant.	)	Case No. 1:19-cv-08402 Judge Virginia M. Kendall

OCTAPHARMA PLASMA, INC.'S OPPOSITION TO PLAINTIFF MARY CRUMPTON'S MOTION TO STRIKE ITS FIRST AND SECOND AFFIRMATIVE DEFENSES

I. INTRODUCTION

Defendant Octapharma Plasma, Inc. ("Octapharma") obtains from screened donors safe, therapeutic plasma that benefits those who may be on an operating room table or in need of convalescent antibodies to fight Covid-19. Pursuant to a comprehensive scheme of federal regulations and utilization of approved medical devices, Octapharma maintains the positive identification of every plasma donor, each accepted donation and confirmation that the donor is not on a list of unacceptable donors. In this action, Plaintiff Mary Crumpton, a former plasma donor, alleges that Octapharma did not comply with Illinois' Biometric Information Privacy Act ("BIPA"), which mandates invade and conflict with the exhaustive federal regulatory scheme that envelopes Octapharma's operations. Furthermore, BIPA itself contains exceptions to its mandates that eliminate conflicts when biometrics are used or stored in a health care setting. Octapharma has properly pled these Affirmative Defenses.

Plaintiff's Motion resorts to the oft-rejected strategy of moving to "strike" these Affirmative Defenses. By ignoring the standards to sustain it, Plaintiff's untimely Motion is an example of why courts disfavor them. Octapharma clearly pled sufficient facts to satisfy its *Iqbal/Twombly* obligations. Plaintiff's challenge to the preemption defense fails to address the facts and the comprehensive federal regulations that govern Octapharma's use of the Template to positively identify donors long after the BIPA-implicated 3-year destruction policy mandated by informed consent. Moreover, Plaintiff's attack on Octapharma's BIPA exceptions fails to apply the ordinary meaning of the Act's phrases. For these reasons, Plaintiff's Motion should be denied.

II. PROCEDURAL POSTURE AND APPLICABLE STANDARDS

On February 3, 2020, Octapharma answered Plaintiff's Complaint. Dkt. 16. As Affirmative Defenses, Octapharma alleged that Plaintiff's BIPA claims were preempted and subject to BIPA

exceptions. *Id.* (Affirmative Defenses Nos. 1 and 2 ("ADs"). On May 28, 2020, Plaintiff sought leave to file a Rule 12(f) motion, which this Court granted on May 29, 2020. Dkts. 36 and 37.

A party seeking to strike from a pleading any "insufficient defense or any redundant, immaterial, impertinent, or scandalous matter" by motion, must do so "within 21 days after being served with the pleading." Fed. R. Civ. P. 12(f)(2) (emphasis added). Courts "disfavor motions to strike affirmative defenses, and only grant them 'if the affirmative defenses are insufficient as a matter of law or present no questions of law or fact.'" *Oleksy v. Gen. Elec. Co.*, No. 06 C 01245, 2013 WL 3233259, at *16 (N.D. Ill. June 26, 2013). "[T]he Court must determine whether the matter is appropriately pled as an affirmative defense and whether it is sufficiently pled pursuant to [FRCP] 12(b)(6)." *Id.* at *7; *see also Microthin.com, Inc. v. Siliconezone USA, LLC*, No. 06 C 1522, 2006 WL 3302825, *9 (N.D. Ill. Nov. 14, 2006). A court must consider a pleadings' attachments, "documents that are critical to the [pleadings] and referred to in [them], and information that is subject to proper judicial notice," along with "additional facts set forth in [the defendant's] opposition briefs" if they are "consistent with the pleadings." *Kenall Man. Co. v. Cooper Lighting, LLC*, 354 F. Supp. 3d 877, 882 (N.D. Ill. 2018). A court should only strike affirmative defenses, "if it appears beyond a doubt" that "no set of facts . . . would plausibly entitle [defendant] to relief." *Mittelstaedt v. Gamla-Cedron Orleans LLC*, No. 12 C 5131, 2012 WL 6188548, at *2 (N.D. Ill. Dec. 12, 2012) (noting the applicability of the *Iqbal*/*Twombly* standard to Rule 12(f) motions). Applying these standards to Plaintiff's Motion, it must be denied.

III. RELEVANT FACTS.[1]

To support its First and Second Affirmative Defenses based on federal preemption and

[1] Octapharma attaches as Exhibit A the Declaration of Monica Byrd ("Dec.") solely to illustrate the facts it will be able to prove, consistent with its Affirmative Defenses. The Declaration gives context to Octapharma's policies and the procedural steps that it undertakes in compliance with applicable regulations. *See Kenall Man. Co.*, 354 F. Supp. 3d at 882 (allowing consideration of additional facts set forth in the

exceptions under BIPA, Octapharma alleged that in ensuring that the plasma it collects and tests from donors is safe to later transfuse into a patient, it must satisfy all applicable regulations under the Food, Drug and Cosmetics Act ("FDA"), Clinical Laboratory Improvements Act ("CLIA") and Illinois' Laboratory and Blood Bank Act ("Illinois Laboratory Act"). Octapharma is licensed under applicable FDA requirements and operates 9 facilities in Illinois. ADs at ¶¶ 1, 5, 8(a) and (j), 9, 37-40; Dec. at ¶¶ 5, 7-9. Plasma is a "biological product," subject to statutory and FDA regulatory minimum requirements that Octapharma satisfies for each donation of plasma, pursuant to its policies developed to meet federal regulation. 21 C.F.R. §606.100. ADs at ¶¶ 3, 7, 8, 8(a)-(j). Octapharma utilizes an FDA-regulated computer donor management software system (the "DMS") to positively validate the identity of each donor, which system creates a unique binary code template derived from a donor's finger scan ("Template"). That Template then relates to the donor and the results of her assessment so that Octapharma can determine if she can provide suitable plasma and be administered red blood cells in an immunization process. ADs at ¶¶ 6, 8(b)(i)(1)-(6), 8(b)(ii)(1), 8(c), 8(g)-(h), 10-23, 25, 27; Dec. at ¶¶ 7, 11-49, 57-64. Octapharma gains the consent of each donor during the screening process pursuant to the FDA regulations. ADs at ¶¶ 6, 8(b)(i)(3)-(6), 8(b)(ii)(1), 8(c), 8(h), 13-23, 25, 27; Dec. at ¶¶ 52-55. Octapharma then utilizes an FDA-regulated plasmapheresis device (the "PCS") that interconnects with the DMS to collect plasma and blood samples for testing by Octapharma's clinical laboratory that is licensed and regulated under CLIA and the Illinois Laboratory Act. ADs at ¶¶ 5, 8(b)(ii)(1), 8(c), 8(d), 8(e),

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defendant's opposition briefs as consistent with the pleadings); *Perez v. PBI Bank, Inc.*, No. 1:14–cv–01429-SEB-MJD, 2015 WL 500874, at *10 (S.D. Ind. 2015); *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n. 1 (7th Cir. 2012) (allowing submission of materials outside the pleadings to illustrate the facts the party expects to be able to prove solely for illustrative purposes and not for the purpose of convert the motion into a Rule 56 motion for summary judgment); *Michael v. Cenlar FSB*, No. 16 C 2010, 2016 WL 4398095, at *1 (N.D. Ill. Aug. 17, 2016) (same).

8(h), 10, 13-23, 24-25, 28, 34-49; Dec. at ¶¶ 6, 10, 57-63. Octapharma's licensed medical professionals also counsel the donor on positive lab test results and release thereof under HIPAA. ADs at ¶¶ 8(b)(iii)(1), 26; Dec. at ¶¶ 64, 69-70. In short, Octapharma's use of the DMS/PCS enables compliance with the FDA, CLIA and Illinois Laboratory Act requirements to maintain for at least 5 years all "Donor History Records", including the Template, cross-referenced to the plasma received, all available for inspection by FDA and other regulators. ADs at ¶¶ 8(f)-(j), 29-33, 38-49; Dec. at ¶¶ 11-12, 71-81.

IV. ARGUMENT

A. Plaintiff's Motion is untimely.

A party seeking to strike a pleading must do so "within 21 days after being served with the pleading." FRCP 12(f)(2). Octapharma filed its Answer on February 3, 2020, making Plaintiff's motion to strike due on February 24, 2020. *See* Dkt. 16. While the Court issued a stay on February 13, the stay was lifted on May 8. Thus, accounting for the 9 days that had already passed, starting on May 9th, Plaintiff had 12 more days – until May 21 – to file her Motion to comply with Rule 12(f)(2)'s 21-day mandate. Thus, even though Plaintiff sought leave on May 28 to file the Motion over Octapharma's objection, Plaintiff's time had expired. Dkt. 36. Nor did Plaintiff cite any excusable neglect to justify the untimely filing. *See id.*; FRCP 6(b)(1)(B).

B. Octapharma adequately pled its First Affirmative Defense.

Octapharma pled that BIPA's mandates are preempted because its requirements cannot be reconciled with the rigorous and specific requirements mandated by the FDA. Octapharma's policies are designed to meet the FDA's requirements to ensure that the plasma it accepts from its approved donors can be tracked utilizing a donor's Template in its implementation of the DMS and PCS to positively validate a donor's identity and be accessible to regulators. A Rule 12(f)

motion can only be granted if there are *no* alleged facts capable of supporting the defense. *See Mittelstaedt*, 2012 WL 6188548, at *2; *see also Kenall Man. Co.*, 354 F. Supp. 3d at 882. To support preemption, Octapharma alleges facts that show collection of the Template by Octapharma satisfies the FDA-required system for validating its donors' identities. ADs at ¶¶ 6, 8(b)(i)(1)-(6), 8(b)(ii)(1), 8(c), 8(g), 8(h), 13-23, 25, 278(b)(i)(1)-(2), 8(g)-(h), 10-23, 25, 27; Dec. at ¶¶ 9, 11-56, 59, 65-69. *See also* 21 CFR §§ 11.10, 11.30 and 11.200 (providing controls for validating donor records containing electronic signatures based on biometrics). Further, Octapharma has pled it must cross-reference and maintain the Template and Donor History Records for **five years** and make it available to regulators. ADs at ¶¶ 8(f)-(j), 29-33, 38-49; *See* Dec. at ¶¶ 11-12, 71-81.

Octapharma pled that it collects and uses the Template pursuant to Section 640.65(b)(3) which provides:

> (3) A donor identification system shall be established that ***positively identifies each donor and relates such donor directly to his blood and its components*** as well as to his ***accumulated records and laboratory data***. . .[and] ***shall . . .*** be used on each visit to ***confirm the donor's identity*** [and provides] ***assurance of positively identifying the donor***. (emphasis added).

During rulemaking, the FDA's comments on this system are telling:

> We have ***finalized the rule to require*** that . . . proof of identity of the donor [be obtained] prior to donation. . . . We believe that . . . ***validated biometric means***, or other means can be useful in establishing the donor's identity...." 80 Fed. Reg. 29842, *29869 (2015) (emphasis added).

Thus, the FDA clearly addressed *biometrics* and required their inclusion if collected among the Donor History Record that Octapharma must maintain. *See id.*; 21 C.F.R. §§ 600.12, 640.65(b)(3), 630.10(g)(1), 640.72. Specifically, "[f]or each donor, establishments *must maintain records including a separate and complete record of initial and periodic examinations, tests, laboratory data, and interviews*, etc.,… as required… in § 640.65…." 21 C.F.R. § 640.72(2)(i) (emphasis added). And those "[r]ecords shall be retained… to permit the return of any clinical report of

unfavorable reactions. ***The retention period shall be no less than five years after the records of manufacture have been completed or six months after the latest expiration date for the individual product***, whichever represents ***a later date***. 21 C.F.R. § 600.12(1) (emphasis added).

Thus, the FDA determined the appropriate time period to keep the Donor History Record to evidence identity validation and when eligibility and suitability determinations were made. *See id.*; *see also* ADs at ¶¶ 8(e)-(h), 10-33; Dec. at ¶¶ 65-81. For the same reasons, the donor's information must be used and shared by Octapharma to protect the plasma supply from a donor who violates donation frequency requirements or is "deferred" due to a positive lab test result. *See id.*; *see also* Dec. at ¶¶ 62-65. The FDA's overriding concern is to ensure a donor is accurately identified so that their plasma is safe to use, and any sourced plasma can be traced back to its donor. *See id*. BIPA, addressing privacy concerns, mandates **destruction within three years** and bars sharing it with others without permission. BIPA, 14/15(a), (b) and (d). Yet, in blithely dismissing the Affirmative Defense as "contain[ing] no support in law at all" and "beyond salvaging," Plaintiff fails to address the facts pled, let alone the applicable FDA regulations.

Congress' intent, as implemented through the FDA's regulations, is the starting point for a preemption analysis, and unlike the cases cited by Plaintiff, manifest the FDA's intent in making requirements based on health and safety concerns.[2] Plaintiff ignores the *health and safety* goals of

[2] In *Nelson* and *Costello*, findings of no preemption were based on the analysis of implicated federal statutes' express preemption provisions in light of state law claims based on a statute addressing a different subject than the federal statutes and *were not inconsistent* with the federal statute's provisions. *See Nelson v. Great Lakes Educ. Loan Servs., Inc.*, 928 F.3d 639 (7th Cir. 2019) (holding Illinois consumer protection and tort laws relating to plaintiff's misrepresentation claims and the HEA could exist in harmony); *Costello v. BeavEx, Inc.*, 810 F.3d 1045 (7th Cir. 2016) (holding Illinois statute regarding wages was too tenuous, remote, or peripheral to the "price, route, or service of any motor carrier" preempted by the FAAA). In *Wyeth* and *Mason*, state law failure-to-warn claims were not preempted by FDA labeling requirements. *See Wyeth v. Levine*, 555 U.S. 555 (2009) (finding no preemption of a state's failure-to-warn statute providing that provided for *stronger* health and safety protections) *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010) (finding no preemption since drug manufacturer's label did not warn of risks and the FDA's approved label did not consider those risks).

the FDA regulations as she steers the argument toward a standard for preemption requiring a finding based on the unequivocal Congressional intent to "preempt state *privacy* statutes regulating the collection of biometric identifiers" or to "occupy the field in the area of biometric *privacy*". Mtn. at pp. 6-7. By ignoring the FDA's *health and safety*-based goals, Plaintiff attempts to turn the preemption analysis on its head.[3] When properly analyzed, Octapharma's preemption defense of BIPA is express, implied or implicated by conflict when viewed from what the *federal* regulation of plasmapheresis does in light of the *federal* purpose of health and safety, hence making BIPA's requirements less stringent than the FDA's and thus subject to preemption. *See* *Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1049-50 (7th Cir. 2013) (finding with respect to autodialed marketing calls that the TCPA's narrow intrastate preemption provision did not expressly or impliedly preempt Indiana more restrictive statute regulating interstate robocalls).

Finally, while Section 15(b) of BIPA requires informed consent for use of biometrics, Octapharma follows the FDA's requirement to obtain a donor's consent and electronic signature after educating its donor, addressing the confidentiality of the donor's records,[4] providing the donor an opportunity to ask and get answers to their questions, and giving the donor a chance to withdraw from the process. *See* 21 C.F.R. §§ 630.10(g)(2)(ii)(A)-(F) and 630.3(h)); Dec. at ¶¶ 52-

[3] See Motion at p. 6 (stating Octapharma's affirmative defenses did not "indicat[e] that Congress unequivocally intended to *preempt state privacy statutes* regulating the collection of biometric identifiers).

[4] By way of example, one iteration of Octapharma's informed consent form included "I understand that my information will be kept private to the extent allowed by law. To protect my privacy, Octapharma Plasma Inc. will keep the records under a Donor Number rather than by name. The records will be kept in a secured area. Only authorized Octapharma Plasma Inc. Personnel will have access to my records. Also regulatory agencies (such as the Food and Drug Administration), approved customer regulatory representatives, an approved Institutional Review Board (IRB) and/or their designees may look at these records during their required reviews of the Donor Center. As stated earlier, "positive" tests for infectious disease viral markers may require Octapharma Plasma Inc. to place my name on a list of Deferred Donors and, if required by law, to report my name to the local health department. Because of the need to release information to these parties, I understand that absolute confidentiality cannot be guaranteed. The results of the research tests may be presented at meetings or in publications; however, my name or other facts that might identify me will not be used." *See* Dec. at ¶ 54.

55. Octapharma clearly pled these facts. ADs at ¶¶ 8(b)(i)(2) and (5), 8(b)(ii), 8(e)-(j), 20, 28-32; *see also* Dec. at ¶¶ 52-55, 65-81. The consent Plaintiff complains of as required under BIPA must be based upon the disclosure of a retention period, but that period cannot exceed 3 years. *See* BIPA, §§ 14/15(a) and (b)(2). Plaintiff's argument that the BIPA's informed consent does not conflict with FDA ignores this interplay. Were Octapharma to obtain informed consent that reflects the FDA mandated 5 years, that consent cannot fully satisfy BIPA. *Id*. As addressed below, Octapharma's DMS and PCS are FDA regulated medical devices and that, in order to ensure the safety of plasma, the FDA thoroughly regulates the retention of a donor's identification. Since BIPA mandates records be destroyed sooner, it is preempted.

1. *BIPA is expressly preempted by the MDA.*

Octapharma pleads its compliance with FDA regulations and facts relating to its use of medical devices regulated by the FDA to do so. *See* ADs ¶¶ 8-32; Dec. at ¶¶ 11-12. In implementing the Medical Device Amendments of 1976 ("MDA") to the FDA, Congress "imposed a regime of detailed federal oversight over medical devices" that included a provision for express preemption. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *See* 21 U.S.C. § 360c *et seq.*; 21 U.S.C. § 360k(a). "[W]hen Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations …". *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996). Plaintiff's state law claims under BIPA are preempted because:

(1) "the Federal Government has established 'requirement[s] applicable to'" the device, under FDA "specific counterpart regulations or there are other specific requirements applicable to a particular device under federal law." *Riegel*, 552 U.S. at 322.

and

(2) Plaintiff's claims "rely upon 'any requirement' of [Illinois] law applicable to the [device] that is 'different from or in addition to,' federal requirements and that 'relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id*. at 323 (quoting § 360k(a)).

First, Octapharma's DMS is recognized as Blood Establishment Computer Software

("BECS"), subject to Class II special controls and described as "a device used in the manufacture of blood and blood components to assist in the prevention of disease in humans by ***identifying ineligible donors***, . . . [and] ***by performing positive identification*** . . . [and] may include a ***BECS accessory*** [like a finger scanner], to augment the performance of the BECS…." 21 C.F.R. § 864.9165 (emphasis added). Octapharma's PCS is an Automated Blood Cell Separator device also subject to Class II special controls. *See* 21 C.F.R. § 864.9245. Specific to Octapharma's PCS, its information is transferred into the DMS. Dec. at ¶ 58. The DMS and PCS ensure that the procedural steps under Octapharma's policies, to comply with FDA regulations, are strictly followed, validate the donor's identity as it determines their eligibility and collects their plasma, retain the data for at least 5 years, and maintain the records for FDA regulators. *See* 21 C.F.R. §§ 640.65(b)(3) and 630.10(g)(1), 21 C.F.R. § 864.1; 21 C.F.R. §§ 864.9165 and 864.9245; *see also* Dec. at ¶¶ 11-14, 16-51, 57-61, 65-68, 73-81.

Having determined that the federal government "established 'requirement[s] applicable to'" the DMS and PCS, we turn to whether Plaintiff's claims "rely upon 'any requirement' of [Illinois] law applicable to the [device] that is 'different from" federal requirements and that 'relate[ ] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Riegel*, 552 U.S. at 322. Plaintiff's claim relies on BIPA, **a law that requires data destruction in three (3) years** that conflicts with FDA recordkeeping and investigative disclosure regulations. *See* 740 ILCS 14/10 (a)-(d); 21 C.F.R. §§ 600.12, 600.20, 600.21, 640.65(b)(3), 630.10(g)(1), 640.72.[5] Thus, Plaintiff's attempted application of BIPA is designed to legislate what the DMS and PCS must do with the Templates from Octapharma's

[5] Octapharma notes that Octapharma's disclosures in compliance with the FDA's regulatory requirements also satisfies that the "disclosure . . . is required by … federal law" as excepted in BIPA Section 15(d)(3). *See* 740 ILCS 14/15(d)(3) (allowing disclosures pursuant to existing law).

donors and imposes a requirement under Illinois law that applies to the DMS and PCS that is "different from" FDA requirements and "relates to the safety or effectiveness of the device [and] to any other matter included in a requirement applicable to the device." *See id*. at 323 (quoting § 360k(a)). Thus, BIPA is preempted in this setting. Plaintiff completely ignores the application of the MDA on how Octapharma must comply with each of the FDA's regulations, which forms the basis of its First Affirmative Defense.[6] *See* ADs at ¶¶ 8-33, Dec. at ¶¶ 11-14, 16-51, 57-61, 73-81.

2. *BIPA is also impliedly preempted due to the expansive FDA regulation in the field of plasmapheresis.*

Field preemption exists when "Congress has legislated comprehensively, thus occupying an entire field of regulation and leaving no room for the States to supplement federal law." *La. Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 368 (1986). Conflict preemption arises when (1) it is impossible for a private party to comply with both federal and state regulations ("impossibility preemption") or (2) state law stands as an obstacle to the purposes and objectives of Congress ("obstacle preemption"). *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 899 (2000). State laws may be preempted by both federal statutes and federal regulations. *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (citing cases); *see also Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (stating "[f]ederal regulations have no less preemptive effect than federal statutes."). When the FDA initially promulgated regulations over the plasmapheresis industry in 1973, it stated that "[t]hese regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities."

[6] Plaintiff cites to various FDA preemption provisions that apply to the FDA's regulation of food, non-prescription drugs, cosmetics, and medical devices, but only considers their applicability to the "finger scanners [that] would [not] (as alleged) fall under the FDCA's definition of a "device[,]" as they are not used in the treatment of disease, nor affect the body's structure or function" while ignoring the MDA's applicability to the DMS/PCS devices that Octapharma uses. *See* Motion at p. 6 (citing to 21 U.S.C. § 343-1; 21 U.S.C. § 360k; 21 U.S.C. § 379r; 21 U.S.C. § 379s.).

Hillsborough, 471 U.S. at 714 (quoting 38 Fed. Reg. 19365 (1973).). In *Hillsborough*, the Court evaluated FDA plasmapheresis regulations for implied field preemption and conflict preemption against municipal plasmapheresis ordinances at that time. *See id*. at 714-21. Of note, Octapharma's DMS/PCS systems had not been invented yet. *See* 21 C.F.R. § 864.9165. Consequently, *Hillsborough's* analysis lends scant support to Plaintiff's argument against Octapharma's FDA preemption defense to BIPA – a state statute wholly distinct from plasmapheresis regulations.

While, state and local regulation impacting donors and plasma collection can constitutionally coexist with these federal regulations if it *adds* to the FDA's standards, but BIPA's requirements do not in a critical way. Plaintiff's solution is that Octapharma must avoid the conflict by choosing another method to positively identify donors or destroy the data under BIPA's regime within three years. *See* Motion at p. 8. Not all identity validation processes are equal. *See* Dec. at ¶ 19 (noting visual identification can result in unavoidable false validation, as in the instance of identical twins); *see also New York SMSA Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 106 (2d Cir. 2010) (finding preemption because the FCC clearly "establishe[d] a 'preference' for certain…. technology… [in their regulation] thus… relegat[ing] other technology…[as] inferior…."). In mandating destruction of records within three years, in light of FDA regulations' **five-year** retention period so that records are available to regulators, BIPA creates an impossible conflict for Octapharma and a clear obstacle to the FDA regulations' objectives and goals that would, if not preempted *would* cause "major damage" to the FDA's "clear and substantial" interest in ensuring the United States' plasma supply is safe for the patient on an operating room table or in their recovery from Covid-19.[7] *See Hillman v. Maretta*, 569 U.S. 483, 493 (2013). Plaintiff's BIPA

[7] Plaintiff cites *Aux Sable* for the proposition that mere differences between state and federal regulations *on the same subject* "are not conclusive of preemption,…[and that] the crucial inquiry is whether [the difference frustrates] … achievement of the Congressional objective." *Aux Sable Liq. Prod. v. Murphy*, 526 F.3d 1028, 1032 (7th Cir. 2008). Yet, there, the 7th Circuit found that because the municipal

claim amounts to a collateral attack on the FDA's judgment in approving biometrics to identify donors and setting a five-year minimum retention requirement to protect the quality and safety of the nation's blood and plasma supply and allow for auditing. 38 Fed. Reg. 32048, 32089 (1973); 21 C.F.R. §§ 630.1, *et seq.*, 640.1, *et seq.*; *see Indiana Bell Tel. Co., Inc. v. Indiana Util. Regulatory Comm'n.*, 359 F.3d 493, 497-98 (7th Cir. 2004) (reflecting preempted state statute setting different procedures for network interconnection agreements than federal law and thus, "interfere[d] with the methods by which the federal statute was designed to reach [its] goal.").

BIPA is preempted in this case because it mandates a lower standard of retention than the FDA regulations and Octapharma cannot follow both.

C. Octapharma has properly and adequately pled facts in its Second Affirmative Defense to support the application of the BIPA exceptions.

1. *Octapharma's collection of a finger scan through its DMS/PCS equates to information collected in a "health care setting" and "collected, used or stored for health care treatment", exceptions to BIPA.*

Biometric Identifiers under BIPA do not include "information captured from a patient in a health care setting or information collected, used, or stored for health care treatment, payment, or operations under [HIPAA]." 740 ILCS 14/10.2. Further, "Biometric Information" does not include "information derived from items or procedures excluded [as a] biometric identifier[]." *Id*. As pled and in the ordinary sense of the phrases, the Template that Octapharma collects from a donor falls within the exception, "information captured … in a health care setting," "or information collected, used, or stored for health care treatment" as the Template is collected by Octapharma's DMS along with the medical information provided by a donor. *See* Dec. at ¶¶ 11-14, 16-51, 57-61, 73-81. This is because the use of the word "or" between the phrases means that the Illinois legislature did not

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regulation of a road limited *all* trucks of a certain weight from using a road subject to the Surface Transportation Assistance Act, its regulation was not a reasonable limitation on the STAA and thus preempted. *Aux Sable*, 526 F.3d at 1037.

intend that such information collected in a "health care setting" or "stored for health care treatment" be defined solely under *HIPAA*'s Privacy Rule definitions. *Elementary Sch. Dist. 159 v. Schiller*, 221 Ill. 2d 130, 145 (2006) (finding in statutory construction, the parts of a sentence connected by "or" are to be taken separately.). The disjunctive "or" separating the two phrases results in a clear and unambiguous distinction, negating the "need to resort to other aids for construction." *Brucker v. Mercola*, 227 Ill. 2d 502, 513, 886 N.E.2d 306, 313 (2007) (citing *Henry v. St. John's Hospital*, 138 Ill.2d 533, 541 (1990).). In making her argument, Plaintiff ignores these canons of statutory construction and claims that because Octapharma had argued in an unrelated case that its operations do not fall under HIPAA, then these BIPA exceptions do not apply.[8] Motion at p. 11. That logic ignores the exceptions to BIPA, as pled by Octapharma.

As explained in its Declaration, to satisfy FDA regulations, Octapharma subjects its donors to detailed questionnaires that delve into the donor's personal health history and health-affecting conduct, a medical screening interview, initial and annual "head-to-toe" physical examinations by a Medical Director or physician substitute, and blood and plasma laboratory testing for viral agents. Dec. at ¶¶ 14-15, 23-51, 56-64. Further, if the donor is to be deferred – determined

[8] While Plaintiff argues Octapharma is judicially estopped from making its exception-based Second Affirmative Defense because of prior cases where its stated exclusion as a "covered entity" under HIPAA's Privacy Rule was a factor evidencing it was not a "service establishment" under the Americans with Disabilities Act, Octapharma's defenses are distinguishable from that position. *See Ladd v. ITT Corp.*, 148 F.3d 753, 756 (7th Cir.1998) (stating "the purpose of the doctrine ... is to reduce fraud in the legal process. . .). First, Octapharma's "health care setting" defense is not rooted in HIPAA at all. *See* Sec IV.C.1. *supra*. Second, as argued *infra*, Octapharma's *clinical laboratory* performs a supporting, but different function than accepting and paying donors for their donated plasma and does so under a separate license, thus Octapharma's argument is distinguishable and may be subject to HIPAA. *See* Dec. at ¶¶ 6, 10; *Ladd*, 148 F.3d at 756; *see also Maley v, Octapharma Plasma, Inc.*, No. 12-13892, 2013 WL 3814248, at *4 (E.D. Mich. July 22, 2013) (stating "[Octapharma] is not listed as a covered entity and does not provide a 'service' to the public. . . . [by] accept[ing plasma] from members of the public and pay[ing] them for donating … [i]t does not provide healthcare…." Notably, the "covered entity" exclusion argument was neither referenced nor adopted by the Tenth Circuit in holding Octapharma was covered by the ADA. *See Levorsen v. Octapharma Plasma, Inc.*, 828 F.3d 1227, 1231 (10th Cir. 2016) (holding under its "ordinary meaning" Octapharma was a "service establishment" subject to the ADA.).

ineligible and unsuitable to donate plasma – Octapharma is required to provide counseling to the donor. Dec. at ¶¶ 15, 40, 62-63, 69-70. Tying collection of the Template to all these interactions with a donor under the DMS/PCS falls within the BIPA exceptions of "information collected . . . in a health care setting" or "information collected, used, or stored for health care treatment". 740 ILCS § 14/10. Dec. at ¶¶ 14-15, 24-51, 59-64.

In the Northern District, at least one court has applied the phrase "information captured… in a health care setting" using its plain and ordinary meaning and did not tie that exception to "operations governed under HIPAA". *See Vo v. VSP Retail Dev. Holding, Inc.*, No. 19 C 7187, 2020 WL 1445605, *2 (N.D. Ill. Mar. 25, 2020) (agreeing with disjunctive separation of phrases.). In the context of BIPA, the *Vo* court defined "health care" to include: "[p]reventive, diagnostic, . . . counseling, service, assessment, or procedure with respect to the physical . . . condition, or functional status, of an individual. . .". *Vo*, 2020 WL 1445605 at *2. As Octapharma provides these health-related services and assessments in an appropriate setting, it collects the finger scan Template to validate the donor's identity. Thus, Octapharma's conduct is expressly excepted from BIPA. *See id.*; Dec. at ¶¶ 11-51, 59-64.

2. *Octapharma's collection is also excepted under CLIA and Illinois Laboratory Act requirements which subject its records to HIPAA.*

Because Octapharma also is a licensed clinical laboratory under CLIA and Illinois Laboratory Act, it is subject to those statutes with respect to its records. *See* 42 U.S.C. §§ 262a, *et seq.*, 210 ILCS 25/7-102, *et seq*. Octapharma collects samples of a donor's blood and plasma, tracks the test results and requires results to be reviewed by its licensed medical professional. Dec. at ¶¶ 6, 10, 14-22, 56-64. Under the Illinois Laboratory Act, Octapharma may be required to disclose its laboratory testing results of a donor subject to HIPAA. 210 ILCS 25/7-102(a)(3); Dec. at ¶¶ 70. *See* 77 Ill. Adm. Code 450.1010(b) (to the Dept. of Health); 210 ILCS 25/7-102(a)(3)

(providing a "clinical laboratory" may report results via an electronic health information exchange as permitted by HIPAA); 77 Ill. Adm. Code 450.1010(a)(9); Dec. at ¶¶ 56-64, 70, 78-79. Thus, Octapharma's compliance under CLIA and the Illinois Laboratory Act are subject to HIPAA and exempt its collection of the Template from BIPA.

3. *Octapharma's collection of the Template is excepted under BIPA as it also serves to further validate medical screening and scientific testing.*

Finally, BIPA provides that "[b]iometric identifiers also do not include an . . . image or film of the human anatomy . . . to further validate scientific testing or screening." 740 ILCS 14/10. In determining a donor's suitability to donate plasma in compliance with FDA regulations, Octapharma obtains validation of its donor's identity through the finger scan Template as it medically screens and physically examines the donor and it collects samples of a donor's blood and plasma to perform laboratory tests for viral agents that are reviewed by its licensed Medical professional. ADs at 5, 8(b)(i)(1)-(6), 8(b)(ii), 8(c), 8(d), 8(e), 8(h), 10, 13-25, 34-49; Dec. at ¶¶ 11-51, 56-64. The Template comprises such an "image of the human anatomy," as a binary representation of the image of the finger scan. *See* 740 ILCS 14/10. Since it is collected to validate the donor's identity for the medical screening and the "scientific testing" of their blood and plasma, the collection of the Template is part of the records serving to "further validate" those processes and donor's test results. *See id.*; Dec. at ¶¶ 11-51, 56-64. The Template itself need not be akin to an "x-ray", but only part of the validation process of a test.

IV. CONCLUSION

For all of the foregoing reasons, Plaintiff's Motion under Rule 12(f) must be denied.

Dated: July 17, 2020

Respectfully submitted,

OCTAPHARMA PLASMA, INC.,
Defendant

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CERTIFICATE OF SERVICE

The undersigned, David Reich, a non-attorney, do hereby certify that I caused a copy of the foregoing ***Octapharma Plasma, Inc.'s Response in Opposition to Plaintiff's Motion to Strike*** to be served on all counsel of record via notice from the Northern District of Illinois's CM/ECF e-filing notification system and via electronic mail on July 17, 2020.

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